biogen idec

Dr. Tomas Salmonsson (CHMP chairman)
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

14 May 2013

Subject: Grouped variation EMEA/H/C/000603/II/59G TYSABRI (natalizumab) 300mg Concentrate for Solution for Infusion; withdrawal of variation to extend the indication in relapsing remitting multiple sclerosis patients without high disease activity who are negative for anti-JCV antibodies.

Dear Dr. Salmonsson,

Biogen Idec Limited submitted a grouped variation under this application. I would like to inform you that, at this point in time, Biogen Idec Limited has taken the decision to withdraw one of these variations to narrow the scope of this application. We will withdraw the variation for a change to the marketing authorisation for Tysabri to extend the indication in relapsing remitting multiple sclerosis patients without high disease activity who are negative for anti-JCV antibodies.

The decision to withdraw and narrow the scope of the application was taken since additional data are required to address questions raised during the assessment process of a variation within the group. Whilst the Company has additional data, they are still provisional. The Company continues to believe that Tysabri could offer an important treatment option with this specific extended indication; the intention of this withdrawal is to allow further discussions on the additional data to take place, prior to considering the submission of a revised labelling change in the future. This withdrawal should allow the second submitted variation to the indication within the group to progress without delay.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMEA website.

Yours sincerely,

[redacted]

Biogen Idec Limited